IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

NATURAL ALTERNATIVES INTERNATIONAL, INC.,	)	
Plaintiff,	)	Case No.: 4:11-cv-04511
v.	)	
WOODBOLT DISTRIBUTION, LLC, also known as Cellucor; F.H.G. CORPORATION, d/b/a Integrity Nutraceuticals; VITAQUEST INTERNATIONAL, INC., d/b/a Garden State Nutritionals,	)	
Defendants.	)	

DEFENDANT WOODBOLT DISTRIBUTION, LLC'S REPLY FOR SUMMARY JUDGMENT OF INVALIDITY, AND OPPOSITION TO PLAINTIFF'S CROSS MOTION FOR SUMMARY JUDGMENT THAT PATENTS ARE NOT INVALID AND FOR INFRINGEMENT

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INTRODUCTION

In response to plaintiff, Natural Alternatives International, Inc.'s ("NAI") combined Opposition, Cross-Motion and Motion (D.I. 62), Defendant, Woodbolt Distribution, LLC ("Woodbolt") submits this combined

1. Reply to NAI's opposition to Woodbolt's motion for summary judgment of invalidity of U.S. Patent No. 8,067,381 ("'381 patent") and U.S. Patent No. 8,129,422 ("'422 patent");
2. Opposition to NAI's cross motion for summary judgment that the '381 and '422 patents are not invalid; and
3. Opposition to NAI's cross motion for summary judgment of infringement.

STATUS OF REEXAMINATIONS

Woodbolt filed separate Requests for *Inter Partes* Reexamination of the '381 and '422 patents in the United States Patent and Trademark Office ("PTO"). The PTO, within the last month, issued Orders Granting Reexamination of both patents and also issued Office Actions rejecting all of the relevant patent claims.[1]

The Orders Granting Reexamination expressly state that the requester, Woodbolt, has demonstrated a "reasonable likelihood that the requester will prevail" that the claims at issue are unpatentable, (i.e., invalid). The Office Actions reject *all* of the relevant claims on *multiple alternative grounds*, over the same prior art references relied upon by Woodbolt in its motion for summary judgment of invalidity before this Court. The Orders Granting Reexamination also

[1] Copies of the Order Granting Request for *Inter Partes* Reexamination and Office Action issued July 26 in the '381 patent are attached as Exhibit 1. Copies of the Order Granting Request for *Inter Partes* Reexamination and Office Action issued August 17 in the '422 patent are attached as Exhibit 2.

adopt in every respect Woodbolt's claims that both patents have a fatal priority defect which renders them invalid over NAI's earlier '596 patent. Any one of the alternative rejections alone would have been sufficient to reject the claims.

NAI must respond to the Office Actions in the two reexaminations by September 17 and 26, respectively and Woodbolt may file responses one month after NAI's respective responses. The PTO will take up the reexaminations for further action two months after NAI's responses, i.e., in late November if not earlier.[2]

SUMMARY OF ARGUMENT

A. Invalidity

Woodbolt's motion for summary judgment of invalidity (D.I. 53) amply demonstrated by clear and convincing evidence that the '381 and '422 patents are invalid on multiple grounds, any one of which is sufficient to invalidate each patent. This is confirmed by the fast and unequivocal rejections in the Office Actions in the Reexaminations, on a timeline much earlier than expected.[3]

In its opposition and cross-motion (D.I. 62), NAI makes a desperate attempt to rescue its patent claims from an inevitable finding of invalidity. Contrary to law, NAI's proposed claim construction seek to import additional language, i.e. limitations, into the patent claims in an attempt to avoid the invalidating prior art. Its attempt fails for at least several reasons.

[2] Manual of Patent Examining Procedure (MPEP) §2666.40, first paragraph (8th ed. Rev. 8, July 2010)

[3] Although the MPEP gives the PTO three months to issue an order granting or denying a request for reexamination, the '381 Order issued in less than two months and the '422 Order issued in less than one month.

First, it is impermissible during claim construction to *add* additional limitations to the claims to avoid prior art.

Second, even if adding additional limitations during claim construction were permissible, the claims must be construed the same way for both validity and infringement. But in this case NAI does the opposite. It adds additional limitations to the claims in an attempt to save their validity, while ignoring those same additional features when applying the claims to Woodbolt's accused products in its infringement analysis. Under NAI's proposed claim constructions, it has not demonstrated that Woodbolt's accused products infringe the claims of the two patents.

Third, even if, contrary to law, *all* of NAI's new limitations are added to the claims, the prior art relied upon by Woodbolt and the PTO still renders the claims invalid.

B. <u>Infringement</u>

In its motion for infringement, NAI finds itself on the horns of a dilemma. Indeed it has created a trap from which it cannot escape.

On the one hand, in its Complaints (D.I. 1 and D.I. 1 in 4:12-cv-00194) and in its motions for a preliminary injunction (D.I. 10 and D.I. 14 in 4:12-cv-00194), NAI has accused Woodbolt's three products[4] of infringement based on the claims *as they appear in the '381 and '422 patents.* But these claims are invalid - and NAI knows it – so in its Cross Motion for infringement it doesn't accuse Woodbolt of infringing the original claims, it accuses Woodbolt of infringing its "new" claims containing all the impermissible add-on limitations.[5] This is a clear admission by NAI that the original claims are invalid.

[4] C4 Extreme, M5 Extreme and NO Extreme.

[5] The impermissible new limitations include the requirement that the dietary supplement be used frequently and in high dosages.

But then NAI finds itself stuck on the other horn of the dilemma because Woodbolt does *not* infringe these "new" claims. Woodbolt's product labels do not instruct the user to use the product in some multi-use or multi-dose fashion as NAI requires in its claims to avoid the prior art.

In addition, NAI's infringement theory for the '422 patent poses an additional hurdle which NAI has failed to address. The '422 patent claims a method of using a human dietary supplement. The method can only be performed by an end user of the product. NAI accuses Woodbolt of "inducement" or "contributory" infringement, which requires proof by NAI that Woodbolt induces "direct" infringement by an end user. NAI has failed to demonstrate how the end user performs the '422 patent method and it fails to demonstrate that Woodbolt, on its package instructions or otherwise, provides any instructions to the end user which induce that user to take the product so that the user would directly infringe the patent.

C. <u>Woodbolt is Merely Practicing the Prior Art</u>

All the claims of the '381 and '422 patents are invalid over multiple prior art references, whether construed as they should be according to Woodbolt, or construed in the contrived fashion urged by NAI.

Woodbolt's accused products are nothing more than prior art compositions. They contain the same amount of beta-alanine as compositions disclosed in the prior art forty years ago, and are used no differently than as described in the prior art.

NAI has failed to demonstrate that Woodbolt should not be entitled to summary judgment of invalidity. Consequently it has also not demonstrated that it is entitled to summary judgment of no invalidity. NAI has also failed to demonstrate that Woodbolt's products or their uses infringe the two patents.

ARGUMENT

A. WOODBOLT'S MOTION DEMONSTRATED THAT THE PATENTS ARE INVALID BY CLEAR AND CONVINCING EVIDENCE, AND NAI'S OPPOSITION AND CROSS MOTION DO NOT ESTABLISH OTHERWISE

1. NAI's '381 Proposed Patent Claim Construction Is Unsupported and Thus Impermissible

NAI seeks the following construction for claim 1 of the '381 Patent (Opposition, p 9).

> **A human dietary supplement – meaning an addition to the human diet in a pill, capsule, tablet, powder, or liquid form for effectively increasing the function of tissues when consumed, where the addition is not natural or conventional food,** and [not] a meat or food flavoring, and is not a pharmaceutical product – comprising beta-alanine as a single amino acid, unbonded to a different amino acid.

Woodbolt agreed, for the purposes of its Motion (but not for the purposes of NAI's Cross-Motion) to include the words in bold in claim 1 even though: (1) the term "human dietary supplement" is a statement of intended use and not a proper claim limitation; (2) the terms "pill, capsule, powder" do *not* even appear in the specification of the '381 patent; (3) the expression "not a natural or conventional food" does *not* appear in the specification;[6] and (4) the functional term "…for effectively increasing the function of tissues when consumed" is an improper limitation of a composition-of-matter claim, a functional limitation which adds no patentable weight.

[6] The specification states otherwise at column 3, lines 44-45 (" the … formulation can be … a food) and discloses the benefits of chicken broth, a food, in Example 2.

NAI's contention that the use limitation "human dietary supplement" in claims of the '381 Patent has patentable weight is without merit.[7] On pages 9-12 of its opposition (D.I. 62) Woodbolt cites five cases which it alleges permit a preamble limitation to provide patentable weight to the claim. NAI's position is incorrect. A purported limitation in a "composition of matter" claim (unlike a method or use claim) does not carry patentable weight because the subject matter claimed is simply the composition recited. Its intended use is irrelevant. None of the five cases cited by NAI support its position that the term "human dietary supplement" should be given patentable weight.

While NAI argues that the '381 and '422 patent application file histories contain statements by NAI as to what they intended by the term "human dietary supplement" (see p. 10 of NAI's opposition, D.I. 62), such statements by NAI were not relied on by the patent examiner because there was no "prosecution" of the '381 patent. The examiner simply allowed the application based on the limited amount of prior art of record. That prior art did not include the prior art references on which Woodbolt relies in its motion. Accordingly, such statements do not serve as a basis for claim construction of that term.

Woodbolt again respectfully draws the Court's attention to the Markman Order of Judge Sleet in the 2009 Delaware action, *NAI v. Vital Pharmaceuticals, Inc.*, referred to in Woodbolt's motion on page 6, footnote 7. NAI argues that the 2009 case was between different parties and involves different patents. Those arguments are disingenuous. The prior patents are not different – they are virtually identical to the '381 and '422 patents in all respects relevant here. Like the '381 and '422 patents, they claimed compositions containing beta-alanine and methods

[7] *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997) ("The discovery of a new property or use of a previously known composition, even when that property and use are unobvious from the prior art, cannot impart patentability to claims to the known composition", citing *In re Spada*, 911 F.2d 705, 708 (Fed. Cir. 1990).)

for using those compositions. The composition claims had the same preamble under discussion here. While Woodbolt was not a party to that litigation, NAI was and had an opportunity to be heard, which is all that counts. While Judge Sleet's ruling may not be binding on this Court, Woodbolt respectfully submits Judge Sleet's reasoning is sound and persuasive authority, and relevant to the present issue.

Even with Woodbolt's concession, for purposes only of Woodbolt's motion, NAI was compelled to add not just one but *two* more limitations to claim 1 in its effort to save it from invalidation by three of Woodbolt's prior art references. The two new limitations, (underlined above) are: (5) "not a meat or food flavoring" and (6) "not a pharmaceutical product." [8] [9] However, neither of these limitations appears in the patent specification and it is thus impermissible to add these "new" limitations.

For the purposes of its Motion, but only its Motion, Woodbolt again confirms its agreement to include the bold terms in NAI's claim construction. However, for purposes of Woodbolt's opposition to NAI's Cross Motion, Woodbolt contests the inclusion of each of numbered limitations (1), (2), (3), (4), (5) and (6) set forth above.

[8] While the specification of the '381 patent states that the compositions *may* be pharmaceutical compositions (col. 3, lines 21-25) and pharmaceutical compositions accordingly could have been claimed, NAI cannot save its claim from anticipation by *now* disclaiming pharmaceutical compositions because the proposed limitation describes nothing more than the *negative* of a possible use of the composition. As discussed above, a use limitation in a composition claim carries no patentable weight. *In re Schreiber*, 128 F.3d 1473 (Fed. Cir. 1997)

[9] The three references which NAI seeks to avoid are U.S. Patent No. Re. 39,370 to Pitlet and U.S. Patent No. 3,966,988 to Wilson, both of which disclose supplements containing beta-alanine used as meat or food flavorings (discussed in Woodbolt's Motion (D.I. 53) at p. 16) and European Patent Publication No. 0 280 593 ("EP '593") which discloses human dietary supplements containing beta-alanine used as cancer therapy pharmaceuticals (discussed in Woodbolt's Motion (D.I. 53) at p. 15).

2. <u>NAI's '381 Patent Claims Are Anticipated by Multiple References</u>

Even if, for the sake of argument, the *two* new limitations (5) and (6) are included in the claim (in addition to Woodbolt's concession of the first four limitations), the claims of the '381 patent do not survive a validity analysis because they are anticipated by the Asatoor and Gardner references, in addition to NAI's own '596 patent.

Asatoor reported investigations in which five adults ingested beta-alanine in two tests conducted at an interval of two weeks. The dosage was 25.6 mg beta-alanine per kilogram of a subject's body weight.[10] That dosage is squarely within the recommended range of dosages described in the '381 patent.[11]

Gardner described a test in which the subject ingested 2 grams of beta-alanine. The dosage was thus 25 mg/kg of the subject's body weight and this dosage too falls squarely within the range of dosages described in the '381 patent.[12]

The DeLacharriere patents (discussed in Woodbolt's motion at p. 6, and footnote 8) also disclose a composition containing beta-alanine as a human dietary supplement. NAI takes the position that topical compositions, such as those described in the DeLacharriere patents,

[10] 0.286 m mol of carnosine, and, separately, that amount of its constituent amino acids beta-alanine and L-histidine were ingested by each subject per kg of body weight. (Asatoor, p. 251, first col., lines 7-8). Because the molecular weight of beta-alanine is 89.01, the dosage of beta-alanine is (0.286) (89.01) = 25.6 mg beta-alanine/kg of body weight.

[11] Fig. 8 of the '381 patent describes the administration of beta-alanine, chicken broth and carnosine to human subjects. Beta-alanine is administered at 10-40 mg/kg. The '381 patent states at col. 9, lines 31-33 that the "…beta-alanine dosage can be between about 1 milligram and about 200 milligrams per kilogram body weight…"

[12] Assuming an 80 kg person, as described in the '381 patent at col. 9, lines 50-52, this dosage is 25 mg/kg of body weight. The Gardner 2.0 gram dose likewise falls within the dosage range of 0.08-16.0 grams described at col. 9, lines 50-51 of the '381 patent.

containing beta-alanine, are not "human dietary supplements."[13] NAI's position directly contradicts the wording in its own '381 and '422 patents.

The '381 patent states, in col. 9, lines 21-23, that "compositions of the invention can be orally ingested or infused through the skin using a topical cream or a patch." (emphasis added) The '381 patent further states, at col. 9, lines 28-29, that "the compositions can be a dietary supplement that can be ingested, injected or absorbed through the skin." (emphasis added) The same passages appear in the '422 patent. Accordingly, NAI's own patent specifications state that "dietary supplements" can be a "topical cream absorbed through the skin."

The DeLacharriere patents disclosing topical compositions containing beta-alanine fall squarely within NAI's definition of a "dietary supplement," and are invalidating prior art for both the '381 and '422 patents.

If the improper limitation "not a pharmaceutical product" is omitted from NAI's proposed claim construction, as it should be, the EP '593 reference (which NAI seeks to exclude from consideration by its limitation) also anticipates claims 1-4, 7, 11, 13 and 14 of the '381 patent.[14] So, EP '593, like Asatoor and Gardner, prescribes the same dosage level as the '381 patent.

NAI argues that the claims (e.g. claim 13) require the human dietary supplement to be present in a sufficient amount that it will increase the amount of beta-alanylhistidine dipeptides in the muscles and delay the onset of fatigue. But *all* the prior art references, as shown above, disclose *precisely and exactly* the same amount of beta-alanine provided to their respective test

[13] NAI's Opposition (D.I. 62), p.8, footnote 4.
[14] Example 2 of EP '593 describes a composition containing 30 grams of beta-alanine which is ingested in four equal aliquots. This calculates to a dose of 7.5 grams. The '381 patent at col. 9, lines 50-51 prescribes dosages of between 0.08 and 16.0 grams, so the 7.5 gram dose in the 'EP '593 falls within the range described in the '381 patent.

subjects as is disclosed in the '381 patent – clearly the right amount to achieve *precisely and exactly* the same desired results the '381 patent seeks.

3. NAI's Proposed Claim Construction of the '422 Patent Is Unsupported

The version of claim 12 that NAI would have this Court adopt is as follows.[15]

> A method to avoid or delay the onset of muscle fatigue and increase the amount of beta-alanylhistidine in the muscles by providing the subject (that is not a horse) as a dietary supplement **a large enough amount of the amino acid beta-alanine over a long enough period of time to increase beta-alanylhistidine dipeptide synthesis in the muscle so that the amount of beta-alanylhistidine in the music is increased.**

The bold language is the "new" language added by NAI in hopes that it will distinguish over the prior art references. However, this language is not supported by a fair and proper reading of the specification of the '422 patent. Example 2 and Fig. 8 describe tests on human subjects in which *chicken broth (containing beta-alanine)* and *beta-alanine (not in broth)* were separately administered. In both cases there was an increase in the level of beta-alanine in the blood plasma of the human subjects after a one-time ingestion of the test material, i.e. the objects of the test were achieved. In Example 3, thrice-daily administration at both 10 mg/kg and 20 mg/kg dose levels for a week or two weeks resulted in similar patterns – the plasma level of beta-alanine always returned to base level after about three hours and there was no change in the retention of beta-alanine in the serum at eight or fifteen days. In fact, the specification states: "The response on day 8 of the treatment tended to be less than on day 1 . . ." (col 16, lines 23-25). This evidence from the '422 patent controverts NAI's argument that the claim needs to have the language in bold face above in order to be properly construed, and, it controverts the statements by Dr. Tallon in 2006 referred to in the Opposition at p. 14 in support of its claim construction.

[15] NAI's Opposition (D.I. 62), p 13.

4. <u>NAI's Attempt To Distinguish the Prior Art On The "Inherency" Issue Is Baseless</u>

Despite NAI's assertion to the contrary, it was understood by skilled workers years, even decades, before NAI's alleged invention date in 1996 that:

(1) ingesting beta-alanine will lead to higher levels of beta-alanine in the subject's blood;

(2) the beta-alanine in the blood will be transferred to the subject's muscle tissue;

(3) the beta-alanine in the muscle tissue will form beta-alanylhistidine (carnosine), a dipeptide; and

(4) the dipeptide (carnosine) will serve to delay or avoid the onset of fatigue in the muscle tissue.

That ingested amino acids are transferred from the small intestine to the blood stream and from the bloodstream to the cells of the body – in accordance with steps (1) and (2) - has been taught in high school biology classes and elsewhere for many decades.[16] There is nothing unique about the methods of the '422 patent which impact the normal, necessary and inevitable processes of the body in steps (1) and (2). A composition containing beta-alanine is ingested and the body simply performs functions (1) and (2), as a necessary and inevitable process.

With respect to step (3), NAI's inventors, Harris and Dunnett, contrary to NAI's statements on p 3 of its opposition, did not "discover" that beta-alanine formed the dipeptide beta-alanylhistidine (carnosine) in muscle cells. That fact was known twenty years before NAI made its "invention." Hama, et al., (1976) (Exhibit 9 to Woodbolt's Motion, D.I. 53) described the following experiments in rats.

[16] See Silverstein et al. The Digestive System: How Living Creatures Use Food; Prentice Hall 1970, p. 39, lines 7-13, Exhibit 3.

In vivo intestinal absorption

> The ß-alanine solution was given daily for a week in a dose of 5 g per kg of body weight. As shown in Fig. 2, ß-alanine accumulated in both liver and gastrocnemius muscle. Anserine and carnosine were not detected in the liver, while the concentration of these dipeptides increased in the muscle after ß-alanine administration. ….. [c]arnosine level in muscle of the test animals was 6 times of that of the control animals. This result indicates that the absorbed ß-alanine is used for biosynthesis of ß-alanyl dipeptides. [emphasis added]

> Figure 3 shows the time course of changes in ß-alanine concentration in the blood, liver and gastrocnemius muscle of rats after oral administration of ß-alanine (5 g/kg). ß-alanine is not usually detected in blood by chemical methods, however, ß-alanine level increased strikingly 15 min after its administration. ß-Alanine concentration reached its peak 6 hr after its administration and then decreased during the subsequent 12 hr.

Figs. 2 and 3 of Hama show large increases in carnosine (beta-alanylhistidine) in the gastrocnemius muscle[17] after administration of beta-alanine. Hama thus shows the inevitable result of administering beta-alanine to a mammal. The reference discloses that ingesting beta-alanine will result in increases in carnosine (beta-alanylhistidine) in the muscle tissues.

NAI tries to discredit Hama by alleging that force-feeding rats by introducing beta-alanine into their stomachs is not the same as a human ingesting a dietary supplement and that the dosage level of the rats in Hama is 40 times that recommended in the examples of the patents. These alleged distinctions have no merit.

[17] The gastrocnemius muscle is the calf muscle.

First, the only mammals excluded from the scope of claim 12 of the '422 patent are horses, so rats are clearly within the scope of the claims. Second, NAI attempts to distinguish between force-feeding into the rats' stomachs and normal ingestion of beta-alanine. In either case, beta-alanine is introduced into the rats' stomachs – how it gets into the digestive tract makes no difference. Third, claim 12 of the '422 patent broadly states ". . . *providing* to the subject an amount of [beta-alanine] to blood or blood plasma . . .". The general term "providing" includes force-feeding mammals (other than horses) as well as providing the beta-alanine by regular ingestion. Fourth, the dosage level in the rat does not detract from the relevancy of Hama's teaching of the inherent effect of providing beta-alanine to the rats' stomachs, having it pass into the blood stream and then having it pass into the muscle tissue where it forms the dipeptide beta-alanylhistidine. Fifth, dosage level is not part of any of the claims of the '422 patent and NAI does not even suggest that it be a part of those claims, except insofar as it argues that the subject purportedly needs to take a sufficient amount of beta-alanine over a sufficient time to achieve the desired effect. Hama thus establishes that steps (1) – (3) of the physiological process inevitably take place when beta-alanine is administered to a rat. That leaves the step (4) of inherency – the function of the dipeptide in buffering hydronium ion and thereby avoiding or delaying the onset of fatigue – to be established.

At page 3 of its opposition, NAI gives its inventors, Harris and Dunnett, credit for making that "discovery." That is untrue.

The beneficial and naturally occuring effect of the dipeptide (carnosine) in delaying the onset of fatigue was well known before the NAI "invention" and the inventors Harris and Dunnett admit as much in the '381 and '422 patents. In the "BACKGROUND" part of the

specification of the ‘422 patent (col. 1, line 36 – col. 2 line 42) where NAI describes the prior art, the following statements appear.

> During sustained intense exercise, or exercise sustained under conditions of local hypoxia, the accumulation of hydronium ions formed during glycolysis and the accumulations of lactate (anaerobic metabolism) can severely reduce the intracellular pH. The reduced pH can compromise the function of the creatine-phosphorylcreatine system. The decline in intracellular pH can affect other functions within the cells, such as the function of the contractile proteins in muscle fibers.
>
> Dipeptides (also referred to herein as peptides) of beta-alanine and histidine, and their methylated analogues, which include carnosine (beta-alanyl-L-histidine), ….. are present in the muscles of humans and other vertebrates. Carnosine is found in appreciable amounts in muscles of, for example, canines, camelids and numerous avian species. (‘422 Patent, col. 2, lines 13-29)
>
> It is known that carnosine contributes to hydronium ion buffering capacity in different muscle fiber types, and up to 50% of the total in equine type II fibers.
> (‘422 Patent, col. 2, lines 39-41)

NAI has thus admitted that the beneficial physiological effects of the dipeptide carnosine in muscle cells were well known before Harris and Dunnett [18]made the “invention” of the ‘422 patent. NAI’s admission in the ‘422 patent should prevent them from arguing otherwise in its opposition.

5. <u>NAI’s ‘422 Patent Claims Are Anticipated by Multiple Prior Art References</u>

The prior art, in particular Asatoor, Gardner and EP ‘593 discussed above, describe dosages squarely within the ranges described in the ‘422 patent and Asatoor and EP ‘593

[18] Other prior art, e.g. Setra p. 2, lines 3-7, Exhibit Q to Exhibit 3 to Woodbolt’s Motion (D.I. 53) also recognized this effect.

describe multiple dosing of human subjects in that dosage range. So, the prior art shows providing a large enough amount of beta-alanine over a long enough period to increase . . . dipeptide synthesis.[19]

Hama also anticipates claim 12 of the '422 patent. While Woodbolt did not rely on Hama in its motion, the discussion of Hama above in the "Inherency" section establishes that publication as a complete anticipation of the claim. The Hama reference shows beta-alanine being administered to the rat, the increase in beta-alanine in the rats' blood levels shortly after administration, the accumulation of beta-alanine in the rats' muscle tissue, and, the formation of the dipeptide, beta-alanylhistidine in the muscle tissue. Since NAI has admitted in the '422 patent that the dipeptide in the muscle tissue contributes to hydronium ion buffering and thereby mitigates the effects of sustained intense exercise, it is clear that NAI's inventors, Harris and Dunnett, did not invent anything.

6. <u>NAI's Purported Indicia of Non-Obviousness Do Not Save The Validity Of Its Patents</u>

NAI alleges on page 30 of its Opposition that industry awards and commercial success are indicia of non-obviousness of the patents.

First, indicia of non-obviousness is relevant only where the patents are alleged to be invalid based on obviousness. Where the patents are asserted to be invalid based on anticipation or lack of novelty, as here, indicia of non-obviousness is irrelevant and doesn't save invalidity.

Second, mere industry recognition and awards to inventors working in a particular field have not been recognized to support non-obviousness, particularly where there is no demonstration of nexus between the recognition and awards, and the claimed inventions.

[19] EP '593 discloses even higher dosages used for "etching" treatments (EP '593, Example 1 and paragraph [0018]).

The same is true with respect to commercial success through licensing. NAI has not demonstrated a nexus between the license income and the claimed invention and its value. Significantly, where the proffered evidence of commercial success is a license taken by a company as the alternative to the cost of defending a patent infringement suit, the mere existence of a license is insufficient to overcome a conclusion of obviousness. *EWP Corp. v. Reliance Universal, Inc.*, 755 F. 2d 898 (Fed. Cir. 1985); *Iron Grip Barbell Co. v. USA Sports, Inc.*, 392 F. 3d 1317 (Fed. Cir. 2004).

7. <u>NAI's False Priority Claim</u>

NAI has cooked up a theory to justify its false claims to priority in both the '381 and '422 patents. It seeks the benefit of those false priority claims and accordingly it has the burden of proving that the claims were made in good faith and in compliance with 35 U.S.C. § 120 and according to accepted practice.

NAI has failed to meet that burden. It offers no authority to support its theory that a patent application can have *two effective claims to priority* during its lifetime – one priority claim early in its pendency which refers to and secures the benefit of the filing date of earlier copending applications and which permits it to file subsequent continuing applications (e.g. the Sixth Application) - and a different priority claim, later in its pendency, which applies only to that application.

NAI offers no case support whatsoever for its theory because there is simply no case which has validated its bizarre notion that a patent application can have *two different effective claims to priority*.[20] Section 120 provides that a claim to priority can be amended during the

[20] The cases cited in NAI's Opposition in footnote 23 all relate to applications in a series of applications which either did or did not specifically refer to earlier copending applications, or

pendency of an application but that a later amendment has an effect for that application for all purposes. To the extent that NAI characterizes this as a *nunc pro tunc* effect, that is exactly what it is. NAI's cooked-up theory to support its claim to priority is presented to this Court in bad faith. That bad faith is further evident in a statement made at page 35 of its Opposition (D.I. 62).

> The inventors' statements to the PTO in the applications for the patents-in-suit – that the sixth application is a continuation of the fifth application, **and** that sixth application is a continuation-in-part of the fourth application – were true when they were made and they **remain true** to this day. [emphasis original]

This statement is a complete falsehood and it misleads this Court. As Woodbolt stated in its Motion (D.I. 53, p. 20) the Fourth Application issued as U.S. Pat. No. 6,680,294 on *January 20, 2004* and the Sixth Application was *not* filed until August 29, 2008, *more than four years later*. The Sixth Application, accordingly, was *not* a continuation-in-part of the Fourth Application when it was filed and it is *not* a continuation-in-part of the Fourth Application today.

8. NAI Has Failed To Demonstrate That It Is Entitled To Summary Judgment Of No Invalidity

Woodbolt has presented clear and convincing evidence in its summary judgment motion that the '381 and '422 patents are invalid in view of numerous prior art references not considered by the PTO including NAI's own '596 patent which anticipates all of the claims because of the priority defect. Woodbolt's evidence is more than clear and convincing. It is overwhelming. As described above, NAI's opposition to Woodbolt's summary judgment motion has failed to demonstrate that Woodbolt has not met its evidentiary burden.

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were or were not copending with those earlier applications. But in all the cases, each application in the series had one and only one effective claim to priority.

NAI's cross-motion for no invalidity does no better. NAI certainly has not met its burden to show that it is entitled to summary judgment of no invalidity.

For those reasons, NAI's motion for summary judgment of no invalidity should be denied.

B. NAI HAS FAILED TO ESTABLISH THAT IT IS ENTITLED TO SUMMARY JUDGMENT ON INFRINGEMENT

1. Woodbolt Has Not Waived Its Non-infringement Defenses

NAI's motion for summary judgment of infringement starts with the erroneous premise that, because Woodbolt elected to oppose NAI's preliminary injunction motion on the '422 patent (" '422 PI Motion") on the bases of patent invalidity and of NAI's failure to demonstrate irreparable harm, Woodbolt somehow conceded infringement.

In opposing NAI's '422 PI Motion, Woodbolt merely needed to show that NAI had failed to meet its high burden of proof for entitlement to a preliminary injunction on one of the required elements.[21] Woodbolt elected to demonstrate that the '422 patent was invalid. This alone was sufficient to defeat NAI's '422 PI Motion. Woodbolt's decision to rely only on invalidity was not a concession or admission of infringement.

By the same token, Woodbolt's election to not file a motion for summary judgment of non-infringement was not a concession or admission that Woodbolt's products infringe the '422 or '381 patents. It simply reflected Woodbolt's decision to avoid any liability by attacking validity because it is settled law that an invalid patent cannot be infringed. Woodbolt's election to move to invalidate the patents is all that Woodbolt needed to do to avoid liability.

[21] See *In re Seagate, LLC*, 497 F.3d 1360, 1374 (Fed. Cir. 2007) ("an accused infringer may avoid a preliminary injunction by showing only a substantial question as to validity…")

Also, there is no requirement that a party must "concede" infringement in order to contest validity. If a party has been sued for infringement, to avoid liability that party need only rely on a single defense, or, identify a required proof on which the patent owner has the burden but has failed to carry that burden. A defendant need not establish *both* invalidity and non-infringement, or concede infringement as a condition of contesting and proving invalidity.

Woodbolt has elected to focus its efforts on demonstrating that the '381 and '422 patents are invalid. It has elected to invalidate the patents to remove them from NAI's arsenal of bogus anti-competitive weapons in the marketplace, not only insofar as they threaten the presently accused products, but also for all other products, once and for all.

2. NAI Has Failed to Demonstrate Infringement of the Patents

a. <u>NAI Proposes Inconsistent Claim Constructions In Its Validity And Infringement Positions</u>

Turning now to NAI's motion for summary judgment of infringement, the only submission by NAI is an "Infringement Claim Chart" (D.I. 63-2, Exh. 3) which purports to show how three of Woodbolt's accused products infringe claims 1, 11 and 13 of the '381 patent and claims 12, 14, 16, 17, and 19 of the '422 patent. Although the law requires that patent claims must be construed the same way for both validity and infringement analyses,[22] NAI takes inconsistent and contrary positions in its validity and infringement analyses. These are follows.

1. In an (unavailing) attempt to distinguish the prior art, NAI argues that multiple doses of beta-alanine over time are required, even though the claims do not so require. But, for its infringement contentions against Woodbolt's products, NAI contends that only a single dose of beta-alanine is needed to come within the scope of the claims.

[22] "It is axiomatic that claims are construed the same way for both invalidity and infringement." *Amgen v. Hoescht Marion Roussel, Inc.*, 314 F.3d 1313, 1330 (Fed. Cir. 2003), citing *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 842 F.2d 1275, 1276 (Fed. Cir. 1988)

2. In an (unavailing) attempt to distinguish the prior art, NAI argues that each dose of beta-alanine must be within a certain range (mg/kg of body weight of the user) even though the claims do not so require. But for its infringement contentions against Woodbolt's products, NAI does not specify that any such dose requirement be or is met.
3. In an (unavailing) attempt to distinguish the prior art, NAI argues that the beta-alanine when ingested according to the prior art is not provided to the blood plasma and muscle tissue so as to be "necessarily" effective to increase beta-alanylhistidine dipeptide synthesis in muscle cells. But for its infringement contentions against Woodbolt's products, NAI does not even mention, much less demonstrate, that beta-alanine when ingested is provided to the blood plasma and the muscle tissue and is effective to increase beta-alanylhistidine dipeptide synthesis in muscle cells.
4. In an (unavailing) attempt to distinguish the prior art, NAI argues that the beta-alanine in prior art compositions and methods does not "necessarily" delay the onset of muscular fatigue. But for its infringement contentions against Woodbolt's products, NAI merely states that "beta-alanine inherently [i.e., necessarily and always] increases the beta-alanylhistidine in the muscle tissue to avoid or delay the onset of muscular fatigue."

NAI's infringement analysis is inconsistent with its validity position in at least two ways:

1. It is impermissible to add limitations (e.g., dosage and frequency of dosage) into a claim.

2. It is inconsistent to state that a prior art composition containing beta-alanine does *not* inherently result in delaying onset of fatigue, but that an identical, accused composition *does* inherently delay the onset of fatigue.

NAI cannot construe its claims in opposite ways for validity and infringement purposes. The claims must always be construed the same way. To the extent NAI advances a claim construction in an attempt to avoid the prior art, then Woodbolt's products clearly do not infringe, and NAI has not met its burden to show infringement. If the claims are properly construed, by not adding the additional limitations NAI proposes, then the claims are clearly invalid over the prior art. NAI essentially concedes as much, otherwise it would not have proposed claim constructions which add additional features to the claims in an attempt to avoid the prior art.

NAI's attempt to add additional features to the claims speaks volumes. If the claims as presently worded and construed by Woodbolt already avoided the prior art, NAI would not have proposed claim constructions with the additional features.

b. <u>Woodbolt is Not Inducing or Contributing to Infringement of the '422 Patent</u>

NAI has accused Woodbolt of inducing and contributing to the infringement of the '422 patent by selling its accused products to its customer the alleged direct infringers. In order to prove inducement of patent infringement, or contributory infringement, NAI must first demonstrate that the end users of its products are direct infringers of the '422 patent.

There can neither be inducement of infringement or nor contributory infringement in the absence of direct infringement. *Joy Techs, Inc. v. Flakt Inc.*, 6 F.3d 770 (Fed.Cir. 1993). Thus, in order for a party to be held liable for either inducement or contributory infringement, the patent owner must first prove that some person is directly infringing the patent. In order to prove

direct infringement, the patent owner must either point to specific instances of direct infringement or show that the accused product necessarily and always infringes the patent. *Acco Brands Inc. v. ABA Locks Mfr. Co.*, 501 F.3d 1307 (Fed.Cir. 2007). In addition, the patent owner must prove that the party "induced" that person to infringe. The mere sale of an article that is suitable for substantial non-infringing use does not amount to inducement, unless the seller takes active steps to encourage direct infringement. *Dynacore Holdings Corp. v. Philips Corp.*, 363 F.3d. 1263 (Fed.Cir. 2004).

NAI's showing of infringement is essentially a claim chart (Exhibit 3 to NAI's Cross Motion) (D.I. 62-3) in which certain portions of the labeling and promotional material from Woodbolt's accused products are quoted. However, NAI has not presented a shred of evidence on how the end users actually use the product. Because NAI has failed to demonstrate that end users of its products are direct infringers of the '422 patent, its motion should be denied for this reason alone.

In addition to failing to demonstrate how end users use the product, NAI has not demonstrated that Woodbolt provides instructions to its end users to consume its products *multiple times* in any regimen that NAI now says is necessary to achieve beneficial results. In its infringement claim chart and in its Motion for Preliminary Injunction (D.I. 14 in 4:12-cv-00194) NAI accused three products of infringing the '422 patent, even though the instructions on the packages for these three products are for a *single serving* and there is *no instruction to ingest the product multiple times over a period of time*. So NAI's accusation of infringement is inconsistent with its construction of claim 12 of the '422 patent.

If NAI's proposed claim construction is adopted, NAI can no longer maintain that Woodbolt is inducing customers to directly infringe the '422 patent because its label instructs the

end user how to use the product *once* as a "pre-workout intensifier" and does not instruct the user to use the product *multiple times* to gain the alleged benefit.

For each of the foregoing reasons, NAI's motion for summary judgment should be denied on the '422 patent.

c. <u>Woodbolt's Accused Products Do Not Infringe the '381 Patent Using NAI's Claim Construction</u>

NAI's infringement contentions on the '381 patent do not describe how Woodbolt's recommended dosages are within the scope of NAI's claims as NAI now wishes to have them construed in order to distinguish them from the prior art and to salvage their validity.

NAI's infringement contentions on the '381 patent also do not demonstrate that Woodbolt's instructions include multiple dosages over a period of time, in order to achieve the benefit which NAI contends is needed to distinguish over the prior art. Woodbolt's product use instructions nowhere instruct the user to take multiple dosages over a period of time, which NAI now contends is necessary to achieve the benefit of its claimed invention over the prior art.

For these reasons, NAI has not established that Woodbolt's accused products fall within the claims of the '381 patent as NAI now wishes to have them construed in order to distinguish them from the prior art and salvage their validity.

C. Woodbolt Is Merely Practicing the Prior Art

The beta-alanine dosage in a single dose serving of Woodbolt's accused products M5 Extreme and N0 Extreme is the same as in the Asatoor and Gardner references. The M5 Extreme label and the N0 Extreme label state that there is 2000 mg of beta-alanine in a serving. If an end user (80 kg) consumes a serving of these products, the dose is 25 mg per kg of body

weight, the same as the dose provided by Asatoor and Gardner to their test subjects. Thus Woodbolt's products are nothing more than prior art products, used in prior art methods.[23]

To the extent that NAI asserts that Woodbolt's products and their use infringe the '381 and '422 patents, the patents are invalid in view of the prior art. NAI cannot have it any other way.

D. NAI's Criticism Of The Reexamination Proceedings Are Inaccurate And Misleading

NAI states in its opposition that it is ironic for Woodbolt to pursue reexaminations when Woodbolt asserted that the PTO did a poor job issuing the patents originally. In fact, the PTO issued the patents because NAI filed a false priority claim. If NAI had been truthful about the priority disclaimers during the original examinations, the PTO would have rejected all of the claims, just as it now has done now in the reexaminations when presented with the correct facts.

The PTO does not have the same incentive and ability to locate prior art reference as do parties against whom patents are asserted. This is precisely why the validity of issued patents can still be challenged in court and be subject to reexamination. Now that the PTO has been provided with prior art more relevant than the prior art it considered when it examined the patents originally and has the correct facts on the priority issue, it is eminently well equipped to perform its duties according to the *inter partes* reexamination statutes, 35 U.S.C. 311, et. seq., and is already well on its way towards performing those duties.

The primary criticism of the PTO is not that it makes poor decisions, but rather that it issues patents without having considered all of the available prior art and information relevant to patentability. But that is mostly because it does not have the resources to locate all relevant prior

[23] The dose of beta-alanine in a serving of C4 Extreme (80 kg end user) is 18.9 mg/kg.

art, and, may not be provided with all of the relevant prior art by applicants and others working in the field. When the PTO does have all the prior art and other relevant information available, it is well equipped and has the expertise to evaluate all the relevant information and make a sound decision on whether claims are patentable.

It is noteworthy that Woodbolt's '381 and '422 patent Reexamination Requests were assigned to different patent examiners within the PTO and that each Reexamination Order and Office Action was signed-off by two additional PTO examiners. These two Reexamination Requests provided *new* information relevant to patentability *not previously found and considered* by the PTO during examination of the '381 and '422 patents. Some of that new information comprises technical publications in the 1970s timeframe. These publications were not in electronic form easily locatable later through electronic search methods. But they are still prior art under 35 U.S.C. 102, which NAI does not contest.

The PTO has now also considered the correct facts regarding NAI's priority disclaimer, facts which NAI misrepresented during the prosecution of the '381 and '422 patents and which it now seeks to justify and defend without a shred of authority. Indeed, the only reason why the PTO issued the '381 and '422 patents originally was because it relied on NAI's misrepresentations of priority and because it did not have before it the new prior art Woodbolt provided in its Reexamination Requests. But the PTO now has this new prior art and the correct facts on how NAI misled the PTO about its priority claim. The new prior art and correct facts on the priority claim render all of the patent claims at issue invalid on multiple, independent grounds.

NAI also alleges that a grant of a reexamination by the PTO has no "probative effect", citing a 1996 case. That cited authority is misleading to this Court, because in 1996 the test for

reexamination was simply whether the requester presented a "substantial new question of patentability" ("SNQ" test). That prior SNQ test was easy to meet, and was satisfied by simply presenting a new prior art reference or combination of prior art references, presenting a "new issue" not considered during the original examination. And the test did not require that there be a likelihood of success that the new art would invalidate a claims of the patent. Indeed, the low bar under this former SNQ test is one of the reasons why the test was made more strict and harder to meet in 2011. The test now applied by the PTO in deciding to grant reexamination requests, the tests applied in both of Woodbolt's requests, is whether the requester "has a reasonable likelihood that it will prevail." Hence, because Woodbolt's requests satisfied the newer stricter test, more probative weight should be given to the PTO having granted the present reexamination requests, especially in view of the numerous alternative rejections of all of the claims.

NAI also alleges that only 10% of the reexaminations resulted in *all* claims being cancelled or disclaimed. That statistic is very misleading in that it mostly reflects reexaminations under the former and easier-to-meet SNQ test. With the newer stricter test for being granted a reexamination as here, that percentage will likely be even higher in the future.

NAI also trivializes the likely impact of reexaminations, in stating that only 10% of all claims are cancelled in reexamination. The likely impact is much greater, even according to NAI's own cited statistics. Those same statistics report that only 11% of patents in reexamination have all claims surviving unchanged, which means that 89% of reexamined patents have at least one claim cancelled or changed in view of the prior art. Even if only one claim is cancelled or changed, that claim is certain to be an independent claim, because the independent claims are always the broadest in scope and would be the first to be affected by the

prior art. The independent claims would also be the claims which most impact an infringement analysis, because a dependent claim cannot be infringed unless an independent claim is also infringed. So, 89% of the reexaminations result in a claim canceled or changed which would impact an infringement analysis of an accused product.

NAI argues that the PTO will take too long and that Woodbolt is seeking to delay a determination of validity of the patents by having the PTO determine the validity issues. To the contrary, the PTO will move quickly in the reexamination proceedings. NAI must respond to the Office Actions in the two reexaminations by September 17 and 26, respectively. Woodbolt may file responses one month after NAI's respective responses. The PTO will take up the reexaminations for further action two months after NAI's responses, i.e., in late November.[24] If the PTO maintains the rejections, as expected by Woodbolt, it will issue a second Office Action, expected in early December, which action is "ordinarily" an Action Closing Prosecution ("ACP") similar to a "final" rejection.[25]

If NAI was truly concerned about speedy action in the reexaminations, it could readily accelerate the reexaminations even more, by responding earlier than September 17 and 26, in which case the PTO would issue its ACP even earlier. NAI could simply present the same arguments that it presented in its Opposition and Cross-Motion here. It has had Woodbolt's prior art and priority defense since the '381 Reexamination Request filed on May 31.

Further, to the extent that the PTO reexaminations are not already moving fast enough for NAI, the PTO would move even faster if this action were stayed, because the PTO would be

[24] Manual of Patent Examining Procedure (MPEP) §2666.40, first paragraph (8th ed. Rev. 8, July 2010)

[25] Manual of Patent Examining Procedure (MPEP) §2671.02 (8th ed. Rev. 8, July 2010) ("…it is intended that the second Office Action in the reexamination proceeding will ordinarily be an ACP.")

obligated to prioritize the reexaminations on its fastest track.[26] If NAI truly believes that its arguments (the same arguments NAI has made to this Court in its Opposition and Cross-Motion), in its responses to the Office Actions are so strong they will result in the PTO entirely reversing itself and withdrawing all of the multiple alternative rejections then the PTO will issue a finding of patentability favorable to NAI in early December.

Whether Woodbolt or NAI prevails in the reexaminations, the reexaminations could be concluded, save for any appeal, within four months. Because the PTO can act quickly, and NAI can expedite the reexaminations even faster, speed in the PTO is not an issue. The real reason that NAI seeks to avoid the reexamination route in the PTO is that the PTO is already on a certain course to invalidate its patents. The reexaminations will inevitably proceed regardless of the action this Court takes in the present motions on validity of NAI's patents.

It is also noteworthy that the PTO ordered both reexaminations much earlier than the three months provided in the MPEP. The PTO issued the '381 Reexamination Order and Office Action in less than two months and issued the '422 Reexamination Order and Office Action less than one month. The PTO clearly and quickly grasped the issues and had no trouble finding that the Reexamination requests established a "reasonable likelihood that [Woodbolt] will prevail" with respect to the patent claims at issue. The PTO has rejected the claims on multiple, alternative grounds, based on the new prior art not previously considered by the PTO and based upon NAI's defective priority claim with which NAI had misled the PTO to issue its patents.

The fast action by the PTO in granting reexamination earlier than expected and required indicates not only that the PTO understood the issues, but also that it is prepared to move quickly to bring the reexaminations to an early resolution, contrary to NAI's arguments in its Opposition.

[26] Manual of Patent Examining Procedure (MPEP) §2686.04 (8th ed. Rev. 8, July 2010)

NAI cites to *Quad Envtl. Techs. Corp v. Union Sanitary Dist.*, 946 F.2d. 870 (Fed. Cir. 1991), which stated that "courts are the final arbiter of patent validity and, although courts may take cognizance of, and benefit from, the proceedings before the patent examiner, the question is ultimately for the courts to decide, without deference to the rulings of the patent examiner." This cite is also misleading to this Court, in that it implies that the court can find a patent *valid* after a patent examiner finds a patent *invalid* during reexamination, which is clearly not permitted. The real meaning of the quote is that a court can find a patent *invalid* even though a patent survived reexamination. In the *Quad* case, the Federal Circuit actually admonished the district court for not revisiting invalidity issues even though the patent there survived reexamination.

CONCLUSION

In view of the foregoing, defendant Woodbolt respectfully requests that its motion for summary judgment for invalidity be granted, that plaintiff NAI's cross-motion for summary judgment for no patent invalidity be denied, and that plaintiff NAI's motion for summary judgment for patent infringement be denied.

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Dated: August 24, 2012

IN THE UNITED STATES DISTRICT COURT

FOR THE SOUTHERN DISTRICT OF TEXAS

CERTIFICATE OF SERVICE

I hereby certify that on August 24, 2012, I caused the foregoing document to be electronically filed with the Clerk of Court using CM/ECF, which will send notification of such filing to all counsel of record.

/s/ Michael Scarpati